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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

PROUTY, REBECCA E

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/527,830	Applicant(s) NAKASHIMA ET AL.	
	Examiner Rebecca E. Prouty	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 October 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 2 and 9-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-8 and 15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 March 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/05</u> . | 6) <input type="checkbox"/> Other: _____ |

Claims 1-14 and newly presented claim 15 are still at issue and are present for examination.

Applicants' arguments filed on 10/16/08, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Claims 2 and 9-14 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 1/11/08.

Claims 5 and 8 are objected to because of the following informalities: the phrase "under the condition phosphorus being restricted" in claim 5 is grammatically awkward. "under conditions where phosphorus is restricted" is suggested. "unit" in claim 8 should be "units". Appropriate correction is required.

Claims 3 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 is confusing in the recitation of "a species" of the specific substrate control rate as it is unclear how a rate comprises species. Was a "species of oil or fat" intended? This is presumed for further examination.

Claim 15 is confusing in the recitation of "said copolyester comprises hydroxybutyric acid" as hydroxybutyric acid is not a copolyester. Did applicants intend this to recite "said copolyester comprises hydroxybutyric acid units"? This is presumed for further examination.

Claims 1, 3-8 and 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The rejection is explained in the previous Office Action. However, those portions of the rejection drawn to insufficient description of the genera of oils or fats or of "a constant value of the specific substrate feed rate" are withdrawn.

With regard to the rejection for lack of description of methods of producing the entire genera of copolyesters applicants argue that although P(HB-co-3HH) is described as an

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example, the specification states "there is no particular limitation on a copolyester capable of being applied to the culture method of the present invention, as long as it is a copolyester that may be obtained by polymerization of at least two monomeric units. However, this is not persuasive because merely a statement something is within the scope of the invention is insufficient to show that applicants were in possession of the subject matter. As discussed in the written description guidelines the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. A representative number of species means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. In this case applicants have disclosed on a single

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representative species i.e., p(HB co HH) which clearly is not representative of the entire genus of biodegradable copolyesters. The recited genus is enormously broad including a infinite number of possible chemical compounds with any structure that includes suitable functional groups for creating a polymer with ester linkages. Different polyesters have very different characteristics would require different microorganisms and/or polymerases for producing. At best applicants disclosed species is representative of methods of producing other polyhydroxyalkanoate (PHA) copolyesters.

Claim 3 is further rejected for lack of description of sufficient species of "controlling the composition of the copolyester by selecting the species of substrate" as the specification fails to present any identifying characteristics of oils or fats which result in high levels of incorporation of the non-HB monomer of the PHA copolyester. Applicants specification discloses only a few specific oils and fats and shows that the levels of incorporation of the non-HB monomer of the PHA copolyester differs substantially for different specific fats and oils but fails to provide any means of identifying how the composition of the copolyester will be modified for other species of fats and oils such that a skilled artisan who wished to produce a copolyester of a particular composition would have

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no ability to select a suitable fat or oil beyond simply random testing of all possible species. As such the specification fails to provide sufficient disclosure to practice the method of claim 3. Applicants should note that this rejection applies only to controlling the composition of the copolyester by selecting the species of substrate and not to controlling the composition of the copolyester by selecting the value for the specific substrate feed rate as the specification provides ample evidence as to how the levels of incorporation of the non-HB monomer of the PHA copolyester vary with the specific substrate feed rate and sufficient indication that these patterns are maintained for all fats and oils in a similar fashion such that a skilled artisan would expect to be able to select an appropriate value of specific substrate feed rate for other fats or oils.

Claims 1, 3-8 and 15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for method of producing a polyhydroxyalkanoate copolyester by culturing a microorganism which comprises controlling a specific substrate feed rate of an oil or fat to be used as a carbon source at a constant value throughout the whole culture period, wherein the microorganism is a microorganism capable of producing said polyhydroxyalkanoate copolyester, does not

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reasonably provide enablement for method of producing any copolyester by a culture of a microorganism which comprises controlling a specific substrate feed rate of an oil or fat to be used as a carbon source at a constant value throughout the whole culture period, wherein said copolyester is a biodegradable copolyester, and wherein the microorganism is a microorganism capable of producing said copolyester. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims broadly recite methods of producing any biodegradable copolyester using an oil or fat as a carbon source for a microorganism capable of producing the copolyester. However the genus of copolyesters is a enormously broad genus of chemical compounds having a infinite number of possible chemical compounds with any structure that includes suitable functional groups for creating a polymer with ester linkages. Different polyesters have very different characteristics and would require different microorganisms and/or polymerases for producing Furthermore, most monomer units necessary for other copolyesters to be produced would not necessarily be produced by all microorganisms and neither applicants specification nor the art

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provides any guidance for selecting microorganisms which can utilize any oil or fat as a carbon source and have the necessary metabolic pathways for the production of any copolyester monomer except those used for the synthesis of polyhydroxyalkanoate copolyesters. As such a skilled artisan could not reasonably expect to produce any biodegradable copolyester using an oil or fat as a carbon source for a microorganism capable of producing the copolyester without undue experimentation to find a suitable microorganism

Claims 3 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of producing a polyhydroxyalkanoate copolyester and controlling the composition of the copolyester by selecting a value for the specific substrate feed rate of an oil or fat used as a carbon source, does not reasonably provide enablement for enabling for methods of producing a polyhydroxyalkanoate copolyester and controlling the composition of the copolyester by selecting a species of oil or fat substrate. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claim 3 recites methods of producing a copolyester and controlling the composition of the copolyester by selecting a

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species of oil or fat substrate and/or selecting a value for the specific substrate feed rate. The specification fails to present any identifying characteristics of oils or fats which result in high levels of incorporation of the non-HB monomer of a PHA copolyester. Applicants specification discloses a few specific oils and fats and shows that the levels of incorporation of the non-HB monomer of the PHA copolyester differs substantially for different specific fats and oils but fails to provide any means of identifying how the composition of the copolyester will be modified for other species of fats and oils such that a skilled artisan who wished to produce a copolyester of a particular composition would have no ability to select a suitable fat or oil beyond simply random testing of all possible species. As such the specification fails to provide sufficient guidance to practice the method of claim 3 without undue experimentation to simply try all possible fats or oils to find one or more which will produce a copolyester with a suitable composition.

The rejection of claims 1, 3-4 and 6-8, under 35 U.S.C. 102(a) as being anticipated by JP2001340078 is withdrawn as the reference does not teach keeping a constant specific substrate feed rate (i.e., a constant value of fat or oil added per net weight of cells).

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3-8, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Satoshi et al. (JP 2001/340078) in view of Naylor et al. (WO 96/25509).

Satoshi et al. describe a process for producing polyester comprising 3HB and 3HH using *Alcaligenes eutrophus* (*Ralstonia eutropha*) using oils or fats as carbon source. Satoshi et al. also describe controlling the molar ratio of 3HH by altering the amount of added oil/fat or fatty acid that is used as a carbon source, the use of coconut oil; palm oil, and palm kernel oil as the oil/fat, a composition of fatty acid comprising 47% lauric acid as a carbon source, the use of microorganisms transformed by a recombination vector that contains the gene of a polyester

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polymerizing enzyme isolated from *Aeromonas caviae*. Satoshi et al. also states that if the oil/fat is added in a large amount at one time, the concentration of dissolved enzyme in the culture liquid may be decreased and because fatty acids are cytotoxic and may inhibit growth. Therefore, a method in which the fatty acid is added in divided amounts such that they do not inhibit growth or a method in which they are added continuously to maintain a concentration that does not inhibit growth is preferred. Satoshi et al. do not teach keeping the a constant specific substrate feed rate (i.e., a constant value of fat or oil added per net weight of cells).

Naylor et al. (WO 96/25509) describe a method of producing a PHA comprising culturing *Alcaligenes eutrophus* in which the carbon source is fed gradually to avoid a toxic concentration of substrate and to maintain a constant oil uptake rate (i.e., 0.13g/g of non-PHA cell mass/hr (see page 7)). Thus Naylor et al. are in fact maintaining a constant specific substrate feed rate of the carbon source. Naylor et al further teach that phosphorus restriction can be used to increase PHA accumulation (see page 4). Naylor et al. teach that their fermentation conditions produce high yields of PHA.

Therefore, it would have been obvious to one of ordinary skill in the art to apply the carbon source feeding strategy of

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Naylor of the PHA culture methods of Satoshi et al. in order to increase the yield of PHA.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rebecca E. Prouty whose telephone number is 571-272-0937. The examiner can normally be reached on Tuesday-Friday from 8 AM to 5 PM. The examiner can also be reached on alternate Mondays

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nashaat Nashed, can be reached at (571) 272-0934. The fax phone number for this Group is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rebecca Prouty/
Primary Examiner
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